DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

April 19, 2002

Ref: 2002-DAL-WL-15

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. George Worley, President and CEO
Beta Biomedical Services, Inc.
3301 Century Drive, Suite E
Rowlett, Texas 75088

Dear Mr. Worley:

Our review of information collected during an inspection of your firm, located in Rowlett, Texas, on December 6 through 11, 2001, and of the promotional materials posted on your firm's website at www.betabiomed.com revealed that your firm rebuilds, repairs, replaces, and converts a variety of OEM pulse oximeter sensors into other types of sensors, which it ships in interstate commerce in packaging bearing your firm's name. These products are devices as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The FDA considers your firm to be manufacturing devices with respect to your conversion of OEM pulse oximeter sensors. See 21 CFR 807.3(d). When your firm changes an adult sensor to a pediatric sensor or vice versa, you are changing the intended use/patient population of the device. You may also be affecting the device's performance and safety specifications. Likewise, when you change an adult sensor intended to be applied to one part of the body to an adult sensor intended to be applied to a different part of the body (e.g., changing a finger sensor to an ear sensor, or a finger sensor to a site to site sensor) or similarly change a pediatric sensor, you are changing the intended use of the device. You may also be significantly changing the device's performance and safety specifications because sensors applied to different parts of the body may have different accuracy specifications with regards to arterial oxygen saturation and pulse rate.

Because of these changes in intended use, the devices resulting from these conversions are new devices which your firm is introducing into commerce for the first time. They are not covered by the premarket notifications held by the OEMs who manufacture the devices from which your converted sensors are derived.

The law requires that manufacturers of medical devices obtain marketing clearance or approval for their products from the FDA before they can distribute them commercially. See 21 CFR 807.81(a)(2). This helps protect the public health by ensuring that newly introduced medical devices are safe and effective for their intended uses. Because you have not submitted 510(k)s for the above changes, your converted sensors are misbranded under Section 502(o) of the Act. Until such time as you submit 510(k)s and obtain FDA clearance, your remanufactured oximeter sensors are also adulterated under Section 501(f)(1)(B) of the Act, in that they are Class III devices under Section 513(f) and do not have an approved application for premarket approval (PMA) in effect pursuant to Section 515(a), or an approved application for investigational device exemption (IDE) under Section 520(g).

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or assessing civil money penalties. Also, until these violations are corrected, and the FDA has documentation to establish that such corrections have been made, federal agencies will be advised of the issuance of this warning letter so that they may take this information into account when awarding government contracts.

Please be aware that your firm's rebuilding, repair, and replacement activities may also constitute manufacturing, if they significantly change a finished device's performance or safety specifications, or its intended use. Compare 21 CFR 820.3(w), which defines "remanufacturer" as any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use, and 21 CFR 820.3(o), which defines "manufacturer" to include remanufacturers. When you change the housing unit or finger pads or cable of an OEM pulse oximeter sensor, or a combination of the above, to components manufactured for Beta Biomed (or, replace non-functioning diodes with those taken from scrap OEM devices), you may significantly change the performance specifications, safety specifications, or intended use of the original manufacturer's device, thus producing a new device requiring its own premarket clearance or approval.

We also request that you identify any devices that your firm services that are intended by the OEM for single use only, and describe what services are available. For guidance on how the FDA regulates reprocessors of devices intended for single use only, see the Guidance Document "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals." This document can be found at http://www.fda.gov/cdrh/reuse/index.shtml

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to assure that violations similar to those identified above will not recur and to provide the requested information. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Your reply should be directed to Thao Ta, Compliance Officer, at the above letterhead address.

Sincerely yours,

Michael A. Chappell
Dallas District Director

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